EXHIBIT D

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re:
Bair Hugger Forced Air Warming
Products Liability Litigation

This Document Relates To:

All Actions

MDL No.
15-2666 (JNE/FLN)

VIDEOTAPED DEPOSITION

OF

SCOTT D. AUGUSTINE, M.D.

Minneapolis, Minnesota

Friday, March 31, 2017

Reported by:
Amy L. Larson, RPR
Job No. 121237

time you had any interactions with him?
A. I don't recall.
Q. How about Dr. Andrew Legg, have you ever met Dr. Legg?
A. No.
Q. Have you ever had any direct communications with Dr. Legg?
A. Yes.
Q. When was the last time you had any direct communication with him?
A. I'd have to guess.
Q. More than a year?
A. No, it was at least five years ago.
Q. Okay. When was the last time you had any communication with Dr. Paul McGovern?
A. Again, I'd have to guess.
Q. More than a year?
A. No, I think less than a year. It was last year sometime.
Q. Last year being 2016?
A. Yes.
Q. And what kind of interactions did you have with him in 2016?
A. I had dinner with him.

Q. Where was that?
A. In London.
Q. Was it a social dinner or was it a mixture of social and business or was it a purely business dinner?
A. I would call it a social dinner.
Q. Other than that dinner with him, did you have any other communication with him in 2016?
A. Yes.
Q. What was the nature of your other interactions with him?
A. He is considering publishing another article to clear up the confusion about the change in antibiotics in his first article.
Q. And how do you know that?
A. How do I know what?
Q. That he's considering publishing another article to clear up the issues relating to the antibiotics in his other article.
A. Because we talked about it.
Q. In that dinner in London?
A. Yes.
Q. Did you communicate with him other than at that dinner in London about this -- about

that particular subject?

A. Yes.

Q. Before or after the dinner?

A. I'd have to guess. I don't know.

Q. Okay. Who brought up the issue of the possibility of him publishing another article to clear up the issues related to the antibiotics in his prior article?

A. I did.

Q. How did you bring it up to him? And by that I mean was it in person, by telephone, e-mail, letter?

A. I don't recall.

Q. And what was it you specifically -- that you recall bringing up to him?

A. That 3M, in particular, is making a huge issue of this antibiotic change when, in fact, it had no affect at all. All you have to do is rerun the statistics, publish another article that clears that up, and it would be a great service to human kind.

Q. Were you suggesting that he consider writing such an article?

A. Yes.

AUGUSTINE

MR. BENHAM: Objection to the form of the question, vague and compound.

THE WITNESS: There were studies done to that effect, yes.

BY MR. COREY GORDON:

Q. And you were involved in several of those studies, weren't you?

A. Are you saying me or the company?

Q. Yes, you, Scott Augustine.

A. I'm sure I was at least peripherally involved, yes.

Q. Okay. And you know that several of those studies were published, right?

A. That's correct.

Q. And -- and, in fact, you, for the last several years, have spoken at many conferences and you've written many -- many things for public consumption where you describe the particles that you've counted coming out of the Bair Hugger and the bacteria that you scraped off from the inside of the Bair Hugger, right?

A. That's correct.

Q. But you've never once publicly disclosed that

you tried five times to get live bacteria coming out of the Bair Hugger airstream and couldn't get it?

A. Well, I think we made technical mistakes in that, that's my opinion.

MR. COREY GORDON: Why don't we take a break.

THE VIDEOGRAPHER: We're going off the record. The time is 10:27 a.m.

(Whereupon, a brief recess was taken.)

THE VIDEOGRAPHER: We're back on the record. This is the start of media number 2, and the time is 10:43 a.m.

BY MR. COREY GORDON:

Q. Dr. Augustine, the five times you tried to capture bacteria in the airstream -- coming out of the airstream of a Bair Hugger hose, that would be -- that type of testing would be categorized as aerobiology testing, right?

A. I don't know.

Q. Okay. Do you know what aerobiology testing is?

A. No.

the rest of the pages I could --

MR. COREY GORDON: I'd love to, but I don't have them.

BY MR. COREY GORDON:

Q. Of the ones that are in front of you, though, you've identified everything except pages 3, 6 and 7 as something that you or somebody on your team would have rough drafted?

A. I believe that to be true.

Q. Okay. What was the genesis of this guide? How did it come -- come -- come to be rough drafted?

A. Well, our objective was to teach the world about this problem, and it's a lot more efficient if you can just hand them something that summarizes everything rather than having to go through the whole story one by one.

Q. And by teaching the world, you're talking in this particular case about teaching plaintiffs' lawyers how to sue 3M, right?

A. Teaching anybody that's interested. But if it's a plaintiff's lawyer, it would work for that too.

Q. Okay.

A. I don't know if I even read it. This is just -- I was not involved in this, so I -- I've got plenty on my plate to do and I focus on what I'm working on.

Q. Do you think it's appropriate for your company to have set up a Gmail account that looks like it's from a -- connected to a law firm?

MR. BENHAM: Objection to form.

THE WITNESS: If it's on their behalf and with their permission.

(Whereupon, Exhibit 20 was marked for identification.)

BY MR. COREY GORDON:

Q. I'm showing you what's been marked as Exhibit 20. The bottom e-mail is from your in-house lawyer J. Randall Benham to David Hodges, Gabriel Assaad, your marketing manager Dan Grewe, and you, "Re: Wall e-mail," correct?

A. Correct.

Q. And Mr. Benham says, "David, I think I have now caught up with after the holiday break." Number 1, "The Davis response explaining that

you would not be at the AAJ went out before the 4th," it goes on to discuss something. Number 2, "The Wall response went out this morning." Number 3, "The Volletsen response went out this morning edited as you requested." Number 4, "Calvin Warriner was sent the abridged guide. Warriner and SearcyDenny are such heavy hitters, however, that it might be worth reaching out to them with call or follow-up e-mail from you," goes on to discuss that a little further.

And then it says for number 5, "Kerr/Goldberg has received the guide, but Deborah Kerr has asked for time this week to speak with you by phone." Number 6, Mark Delphin has also asked to speak directly with you?"

When you got this e-mail did you have any questions for Mr. Benham as to why responses to lawyers were going out from your company?

A. No, it didn't involve me.

Q. So if it didn't involve you, you didn't bother to ask anyone what was going on here?

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MR. BENHAM: Objection to form.

THE WITNESS: I mean, not on an issue like this, no.

BY MR. COREY GORDON:

Q. You didn't consider it to be anything out of the ordinary for your company to be responding to lawyers making inquiries to a website that appears to be a law firm's website about products liability litigation against 3M?

MR. BENHAM: Objection to form.

THE WITNESS: I had volunteered our team to help in any way they can.

BY MR. COREY GORDON:

Q. Including ghostwriting materials for the lawyers, right?

MR. BENHAM: Objection to form.

THE WITNESS: Correct.

BY MR. COREY GORDON:

Q. Including setting up and running a website for the lawyers, right?

A. I don't know about that.

Q. Including communicating in the lawyers' names with other lawyers who might be interested,

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MR. BENHAM: Objection to form, calls for speculation.

BY MR. COREY GORDON:

Q. -- to help him come up with questions for Arizant?

A. I don't recall sitting down with Mr. Assaad. Now, if you've got evidence that I did it, put it in front of me and I'll have to say whether I remember it or I don't, but I don't recall that.

(Whereupon, Exhibit 21 was marked for identification.)

BY MR. COREY GORDON:

Q. I'm showing you what's been marked as Exhibit 21. If you begin at the back page, the first e-mail in this chain is from Gabriel Assaad, who writes, "I will be arriving on Tuesday to take the depositions of Hansen, Zgoda and Van Duren, in that order. Are," there's a word missing, presumably you, "and Scott free to meet with me Tuesday night?" Did I read that correctly?

A. Yes.

Q. And Mr. Benham replies with a cc to you, "I am certainly available, and although" -- "although I have not spoken with him, I expect Scott is as well. Perhaps we can meet at our offices as early as is convenient for you." The next paragraph gives details of your office.

And the next paragraph says, "In the meantime, I'll prepare comments about questions for these fellows. I'll send it later today." Do you see that?

A. Yes.

Q. Okay. Now, if you go to the second page at the top, the 4/29 e-mail from Mr. Assaad says, "I'm renting a car, I can meet you at your office. I will call you when I land. In case my flight is delayed, please send an outline of what you think I should ask." Do you see that?

A. Yes.

Q. And the response from Mr. Benham to Mr. Assaad with a carbon copy to Mr. Hodges and you, "I sent some comments earlier, but I will try to elaborate. No problem if your

flight is delayed, we will be here whenever you are available," it goes on to talk about the flight info.

Does that refresh your recollection as to whether you participated in a meeting with Mr. Assaad to help him prepare for depositions take -- to taking depositions of current or former 3M/Arizant employees?

A. Apparently I did.

Q. You have no independent recollection of it though?

A. No.

Q. Do you think -- strike that.

As CEO of Augustine Biomedical + Design, do you think it's an appropriate use of ABD corporate resources to be preparing outlines for lawyers suing 3M to ask questions of current and former 3M employees?

MR. ASSAAD: Objection to form.

THE WITNESS: Yeah, I think that any -- any way we can help. As I've said, I instructed my team to help in any way they could.

BY MR. COREY GORDON:

Q. To help the lawyers build their case against 3M?

A. Absolutely.

Q. Why do you think that was -- that's an appropriate thing for the corporate resources of Augustine Biomedical + Design?

A. Because I'm tremendously frustrated that 3M has acted as recklessly as they have and continued to expose patients to a very high-risk product putting profits ahead of -- of public safety. And since 3M refuses to act responsibly, I need to marshal any help I can get to force it to act responsibly.

Q. Augustine Biomedical + Design has shareholders, doesn't it?

A. Yes.

Q. And you have a fiduciary obligation to maximize the return on their investment, don't you?

A. Yes.

Q. So how does advancing your personal crusade to get 3M to be responsible, advance the corporate interests of Augustine Biomedical +

Design and benefit its shareholders?

MR. BENHAM: Objection to form.

THE WITNESS: Well, certainly, if 3M were to act responsibly, it would be in our best interest as a company.

BY MR. COREY GORDON:

Q. Why?

A. Because forced-air warming is causing all these problems and our current product HotDog does not cause these problems, so presumably we would end up picking up some market share from that.

Q. So the reason you were -- you have been helping the plaintiffs' lawyers build and put together their case and even examine witnesses is because if you can assist in having significant court victories on behalf of plaintiffs against 3M, that will hurt 3M's business and, therefore, help yours?

MS. CONLIN: Objection --

MR. BENHAM: Objection to form.

BY MR. COREY GORDON:

Q. Is that right?

MS. CONLIN: Objection as to form,

also not limited in time or scope. I think you're referencing the West litigation, Mr. Gordon, that's my objection.

THE WITNESS: No, that's not true. The main motivation here is that 3M is infecting patients with my invention, and I feel responsible for that. And that's been my motivation since the beginning. Now, there is a side benefit that corporately will benefit from that, but that's not my main motivation.

Q. Well, in fact, you've tried to identify the hospital and medical personnel involved in every new plaintiff's case that gets filed so you can send your sales team in, right?

A. We've tried to identify them all, yes.

Q. And the sales team goes in and tries to use the fact that a patient who developed a surgical site infection at a particular facility has joined the litigation against 3M as a -- you use that as a sales and marketing tool, right?

A. It's happened in some instances, yes.

Q. Well, you regularly print up lists of the new

cases filed and distribute them to your sales force, right?

A. That is true.

Q. And your sales director exhorts the sales staff to use the fact of these filing -- filed lawsuits to go to the hospitals and try to get them to switch over to HotDog, right?

A. What do you mean by "exhorts"?

Q. Encourages.

A. And that's a true statement then.

Q. Okay. And one of the things that your sales force is instructed to do is to suggest to the hospitals that because -- well, strike that.

One of the sales tactics that -- that your sales team has been instructed to use is to suggest to the hospitals that they might get sued as a result of these cases?

MR. BENHAM: Objection to form.

BY MR. COREY GORDON:

Q. Right?

A. I don't believe that's a true statement.

Q. Okay. Are you aware of any statements that you or anyone else has ever made to anyone in

the medical community to suggest that the hospitals or the doctors themselves were at risk of -- of lawsuits as a result of 3M's invoking the learned intermediary defense in these cases?

A. Yes.

Q. Under what circumstances have you used that -- used that -- strike that.

How have you raised that issue with hospitals or the medical community?

A. Well, I've referred to that in my speeches, in my medical talks.

Q. You were very anxious to have Kennedy Hodges file its first lawsuit against 3M, weren't you?

A. Could you define "very anxious"?

Q. Chomping at the bit?

A. I don't think that's accurate, no.

Q. Okay. You were making representations that -- in public speeches and letters to various people that, boy, a lawsuit is coming down the pike here, they're -- they're gonna get -- you're gonna get sued soon, and you were kind of anxious for Kennedy Hodges to

finally file the first lawsuit, weren't you?

MR. BENHAM: Objection to form, compound.

THE WITNESS: I mean, I -- I predicted that it was going to happen.

BY MR. COREY GORDON:

Q. Well, you predicted it during this period of time when you were working with Kennedy Hodges running their website, the Gmail account in the Kennedy Hodges' name, sending out the guides, meeting with their lawyers?

MR. ASSAAD: Objection to form.

MR. BENHAM: Objection to form.

BY MR. COREY GORDON:

Q. You weren't just passive -- you weren't just passively waiting for them to file a lawsuit, you were actively fomenting the lawsuit, weren't you?

MR. BENHAM: Object to form.

MR. ASSAAD: Object to form.

THE WITNESS: What do you mean by "fomenting"?

MR. COREY GORDON: Pushing,

air-free warming system, but we have nothing to do with these lawsuits and we are only finding out about them from daily Google alerts." Did I read that correctly?

A. Yes.

Q. When you saw this did you contact your son Brent and say, Hey, Brent, actually, we do have something to do with these lawsuits?

A. We don't have anything to do with the lawsuits.

Q. Okay.

THE VIDEOGRAPHER: We're going off the record. The time is 1:37 p.m.

(Whereupon, a brief recess was taken.)

THE VIDEOGRAPHER: Okay. We're back on the record. This is video number 3. The time is 1:40 p.m.

(Whereupon, Exhibit 29 was marked for identification.)

BY MR. COREY GORDON:

Q. Dr. Augustine, I've placed before you Exhibit 29, a document entitled, "MedWatch Report," bearing Bates numbers

AUGUSTINE_000889 through 001102. You're familiar with this document, aren't you?

MR. BENHAM: Are you asking him about the entire document?

MR. COREY GORDON: In general, this MedWatch report about Bair Hugger.

THE WITNESS: This looks like a report that was submitted some years ago to the FDA.

MR. COREY GORDON: All right.

THE WITNESS: I have --

MR. COREY GORDON: Go ahead. Sorry.

THE WITNESS: -- no -- I mean, I can't tell whether this is in good shape and is the whole thing or -- I mean, I don't know, but it looks like a report that was submitted.

BY MR. COREY GORDON:

Q. Who submitted it?

A. Bob Gauthier.

Q. But you wrote it, right?

A. I wrote most of it.

Q. What part did Mr. -- Dr. Gauthier write?

A. I don't know.
Q. And did anyone else have a role in writing it?
A. This was a long time ago. I don't recall.
Q. All right. Why don't you turn to page 4.
A. (Complies.)
Q. You wrote this page, right?
A. As I said, I wrote most of this document, so I probably wrote that page too. I have no recollection of it though.
Q. Okay. Well, in the first paragraph you say -- well, hang on a second. You wrote this with the expectation that it would be submitted to the Food and Drug Administration, right?
A. That's correct.
Q. And you -- your expectation in ghostwriting this for Dr. Gauthier was that the FDA would take some action with respect to the Bair Hugger, right?
MR. BENHAM: Objection to the form of the question.
THE WITNESS: I don't think expectation is the right word, since the FDA

seems to tolerate a lot of stuff from a lot of companies, but my hope is that they would.

MR. COREY GORDON: Fair enough, your hope.

BY MR. COREY GORDON:

Q. You didn't sign it, did you?

A. No.

Q. And you didn't -- there's no where on it that indicates that you wrote most of it, right?

A. I don't believe so.

Q. And you -- have you ever informed the FDA that you wrote most of this?

A. No, it came from Gauthier and it doesn't matter who wrote it.

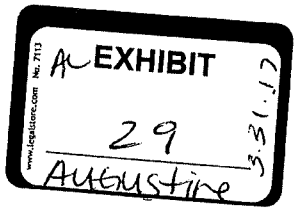
Q. Why didn't you sign it and submit it?

A. Because being a competitor of 3M, they automatically discount competitors.

Q. So you wanted the FDA to pay more attention to this and think of it as a genuine concerned expressed by an independent physician as opposed to something that a competitor was writing; is that right?

MR. BENHAM: Objection to the form of the question.

MedWatch Report



B.5.

Introduction

I am a Board Certified Anesthesiologist with special training and interest in cardiac and pediatric anesthesiology. I spent many years on the academic faculty at the University of Minnesota and have recently moved to private practice. As a practicing anesthesiologist—as well as a clinical researcher—I have observed numerous problems with forced-air warming systems ("FAW") that I believe put patients at risk. Specifically, I have studied Bair Hugger® FAW systems manufactured by Arizant, Inc. The results of much of this research have been disclosed to the executives at Arizant. Despite the fact that they have been aware of these problems for over two years, I have not seen any efforts on their part to correct the problems or to report the problems to either the authorities or to their customers.

Since I helped Arizant (Augustine Medical at that time) develop the intraoperative Bair Hugger product when it was introduced into the operating room about 20 years ago, I feel somewhat responsible for these newly discovered patient risks. I also find Arizant's behavior regarding the safety problems with their products - the fact that they appear to be in total denial regarding these problems-- to be very disturbing. That is why I am compelled to make this complaint to the FDA. This report summarizes my research and that of others as well as information that I have gathered from public sources and from industry.

I will address the following five risks to patient safety:

1. Bacterial contamination of FAW blowers—Multiple published studies, including my own, establish that the internal airflow paths of Bair Hugger blowers are routinely contaminated with multiple strains of pathogenic bacteria and that millions of particles per hour are commonly blown from the Bair Hugger systems into the sterile field.

2. Degradation of filtration—Despite representations by Arizant to the FDA and European regulators that the intake filters on its Bair Hugger blowers are HEPA (99.97% efficient), the efficiency of the filters has recently been reduced to 61.3%. As a consequence, the uncleanable interior of Bair Hugger blowers becomes more easily contaminated—and the contamination is blown into the surgical field.

3. Destruction of laminar flow protection by waste FAW heat—Contaminated hot air escapes from Bair Hugger blankets near the (non-sterile) operating room floor, mixes

with "dirty" air, then rises into the laminar flow currents that are intended to protect patients in ultra-clean surgeries. Not only is the laminar flow protection defeated, but the contaminated air also falls into the sterile field as it cools.

4. Breach of reprocessing standards—Arizant has refurbished thousands of Bair Hugger blowers. As noted above, these blowers are contaminated with pathogens. Arizant, however, does not sterilize—or even clean—the interiors of these blowers before placing them back into service. This creates the risk that pathogens may be transported from one clinical facility to another.

5. Failure to meet FDA reporting obligations—Upon becoming aware of the contamination of its systems, the consequences of the reduction of filter efficiency and the destruction of laminar flow protect caused by its systems, Arizant was required to report these issues to the FDA. It has not done so.

Background

A. Benefits of surgical normothermia

Because of the published research of D. Sessler, A. Kurz and others during the last twenty years, the benefits of maintaining surgical normothermia are undisputed. Normothermic patients spend fewer days in the ICU, require less blood, incur fewer morbid cardiac events, and –most importantly—suffer significantly fewer surgical infections than patients who become hypothermic during surgery. [i]

The benefits of normothermia have been acknowledged globally, and active patient warming has become a standard of care in many countries. In the United States, guidelines issued through the Surgical Care Improvement Project ("SCIP") strongly encourage "active warming" in any procedure lasting longer than one hour. [ii] In the United Kingdom, guidelines promulgated by the National Institute of Clinical Excellence ("NICE") forbid beginning surgery unless the patient's temperature is at least 36°C. The patient may not be released to the ward until 36°C has been restored. [iii]

B. Dominance of Bair Hugger therapy

Disposable forced-air warming blankets—and Bair Hugger therapy in particular—dominate the field. SCIP only recently added electrically conductive warming to its definition of "active warming," finally offering a practical alternative to FAW. According to IMS, however, Bair Hugger therapy commands a US market share of approximately 95%. Virtually all of the Bair Hugger blowers in use in the United States are owned by Arizant and "loaned" to hospitals in return for the purchase of disposable warming covers.

C. Early identification/discounting of risks

Concerns that blowing hot air around the operating theatre could risk patient safety were expressed early in the life of the technology. These concerns were summarily rejected and most clinicians now wrongly believe that the technology is safe. The rejection of the risk first occurred in an invited review of the technology by Sessler published in *Anesthesiology* in 2001. Sessler wrote:

> Surgeons are sometimes concerned that increasing air flow in operating rooms will increase contamination within surgical incisions. All forced-air warming include filters that essentially eliminate bacteria in the heated air. Furthermore, studies have demonstrated that the number of colony-forming units recovered from operating rooms is not increased by forced-air blowers. Finally, use of forced-air heating has been shown to reduce the incidence of surgical wound infection threefold by improving host defense. There is therefore no empirical support for the theory that forced-air heating increases infection risk. [iv] (Emphasis added.)

Unfortunately, the key unsupported assertion made by Sessler —*"All forced-air warming include filters that essentially eliminate bacteria in the heated air."*— was untrue regarding Bair Hugger when the assertion was made. Since then, Bair Hugger filtration has gotten significantly worse. (See Sec. II, below) Additionally Sessler, like everyone else, was focused on the wrong issue – waste air, when the real issue is waste heat. Therefore, any of his opinions regarding the risks of FAW must be suspect

I. Bacterial Contamination of FAW blowers

A. Early research

In the late 1990s and early 2000s, several researchers raised issues regarding the safety of Bair Hugger blowers and demanded design changes. In 1997 M.S. Avidan cultured pathogen organisms from the air blown from 40% of forced-air blowers, stating as follows:

> We conclude that these warming devices are a potential source of nosocomial infection… (and suggesting that a) … microbial filter fitted to the nozzle of the hose could be incorporated into the design of the warmer to reduce the risk of contamination.[v]

In 2002 N. Baker and D, King wrote in a letter to the *Journal of Hospital Infection* that swabs from the exterior and interior of the blower all resulted in "heavy growth of bacteria." Air blowing from the end of the hose grew colonies of coagulase-negative *staphylococci, Bacillus spp., and Micrococcus spp.* "At present," they wrote, "there seems insufficient evidence to justify the routine use of forced air warming units as a intraoperative measure during ultra clean orthopaedic surgery." [vi]

In 2003, M. Scherrer of the Institute for Environmental Medicine and Hospital Epidemiology, University Hospital of Freiburg, noted that "The air emitted from these (FAW) blankets also disturbs the ultra clean field and preliminary investigations have shown an increase of bacteria in the operating field when the warming system is on." [vii]

In 2004, after unsuccessfully fighting outbreaks of *Acinetobacter baumannii* at Leiden University Medical Centre, infection control personnel isolated the bacteria to the filters of Bair Hugger blowers. After the pathogenic dust was removed, the outbreak ended, causing researchers to state:

> After...changing the filters of the Bear (sic) Hugger apparatus, the outbreak came to an end, suggesting that this apparatus was indeed the source of the outbreak. [viii]

Dr. Suzanne Beavers, Epidemic Intelligence Service Officer of the Kentucky Department of Public Health, apparently reached a similar conclusion. In three separate publications (two speeches and a newsletter), Dr. Beavers identified Bair Huggers as a source of infectious outbreaks, repeatedly referring to them as "reservoirs of infection." (Annex A)

B. Recent research

1. In 2009, microbiologists from Stanford University essentially replicated the study done by Baker and King in 2002. They found that the internal air-flow paths of 12 of 29 Bair Hugger blowers cultured positive for pathogens and noted the recommendation that "an additional microbial filter be fitted to the distal end of the BH hose." (Annex B)

2. A 2010 study published in *Orthopedic Reviews* was authored by a team including myself and D. Leaper, the UK surgeon who chaired NICE's Surgical Site Infection Guidance Development Group. Prof. Leaper's team sampled 25 Bair Hugger blowers in their operating room environment. The results:

* Pathogenic bacteria were cultured from the internal air-flow paths of 94% of the blowers.

* 32% of the blowers tested were emitting internally generated airborne contamination in the size range of bacteria.
* 24% of the blowers tested were emitting "significant levels of internally generated airborne contamination."

The contamination, the authors stated, originated inside the blowers. The authors recommended adding a distal hose filter.[ix]

3. Another study by Prof. Leaper's team has been accepted for publication in the *American Journal of Infection Control.* (Annex C) In that study, 52 Bair Hugger blowers were sampled in operating rooms. In summary:

* Micro-organisms were cultured from the internal air-flow paths of 92.3% of the blowers including *Staphylococcus aureus* (13.5%), coagulase negative *Staphylococcus aureus* (3.9%) and methcillin resistant *Staphylococcus aureus* (MRSA) (1.9%).
* 58% of the Bair Hugger blowers tested were found to be internally generating and emitting significant levels of airborne contaminants >0.3 µm in size (germ size), up to 35,272 particles per ft^3 of air (80 million particles per hour).

4. In a recent study (in submission for publication) by Dr. Michael Reed, an orthopedic surgeon in the United Kingdom, 23 Bair Hugger blowers were sampled in operating rooms. The findings:

* Micro-organisms were cultured from the internal air-flow paths of 100% of the blowers including coagulase negative *Staphylococcus aureus* (74%), mold (26%) and *Micrococci* (9%).
* 100% of the blowers were emitting internally generated particles >0.3 µm in size, up to 112,000 particles per ft^3 of air (300 million particles per hour).
* In the most contaminated blower, emitted particle count was 40 times greater than intake particle count.

5. In an abstract submitted to the American Academy of Orthopedic Surgeons 2011 annual meeting by Dr. M Reed, 75 Bair Hugger blowers in active use in 11 hospitals were cultured. Blowers with 93.8% efficient inlet filters were compared to blowers with 63.8% efficient inlet filters. The findings:

* Micro-organisms were cultured from the internal air-flow paths of 100% of the blowers with 63.8% efficient filters.
* Micro-organisms were cultured from the internal air-flow paths of 92% of the blowers with 93.8% efficient filters.

* There was a significant increase in common SSI pathogens (*s. aureus and s. epidermidis*) in the blowers with the lower 63.8% efficient filters (74% v 17%; $p<0.01$). (Annex D)

C. Consequences of contamination

Of course, it is not unusual for medical devices used during surgery to become contaminated. For that reason, the FDA and international regulators have developed strict rules regarding labeling, instructions for use and cleaning protocols that manufacturers must provide.

1. Violation of FDA regulations

Under FDA labeling regulations, 21 CFR 801, a device must have adequate directions, which include instructions on preparing a device for use. Instructions on how to reprocess (i.e., clean, and disinfect or sterilize) a reusable device are important steps in preparing a device for the next patient. Similarly, IEC 60601-1 deems labeling and instructions for use "a critical component of a medical device." An operator's manual is required to provide information on cleaning, preventive inspection, and maintenance to be performed by the user. In addition, the frequency of such maintenance must be specified. Manuals must provide complete instructions to ensure that routine maintenance can be performed safely.

The information provided by Arizant, however, does not even acknowledge the possibility that the internal air-flow path could be contaminated, much less provide instructions as to how the contamination can be abated. Cleaning instructions suggest merely that cleaning staff wipe the exterior of the blower with a damp cloth. [x]

2. Violation of United Kingdom regulations

(a) Health Act of 2006

As recently acknowledged by NICE, Bair Hugger is a two-part device: the paper/plastic blanket is disposable; the blower is reusable.[xi] Reusable devices used in operating theaters are subject to special legal requirements in the UK. The Health Act of 2006 is unambiguous regarding such reusable devices:

Appendix 2, f. -- Decontamination of reusable medical devices

"Effective decontamination of reusable medical devices is essential."
"Reusable medical devices and other devices should be decontaminated in accordance with manufacturer's instructions and current guidelines."

Arizant's Bair Hugger system violates both requirements of the Health Act. The reusable portion of the system—the blower—cannot be effectively decontaminated between surgeries because the contamination is sealed inside the blower. As soon as the blower is activated, the contamination aerosolizes, exiting the blower and spreading into the sterile field.

(b) Medicines and Healthcare Products Regulatory Agency ("MHRA")

The manual of the Microbiology Advisory Committee, a group of experts reporting to the MHRA on disinfection and sterilization practices, confirms the requirement for the decontamination of reusable devices:

> Manufacturers of reusable medical devices are required by the Medical Devices Directive to supply clear written decontamination instructions, which should include appropriate cleaning, disinfection or sterilization methods.[xii]

As noted, Arizant offers no instructions for decontamination whatsoever. The Bair Hugger Operating Manual suggests only that the outside of the blower box be wiped with a damp cloth. Having worked at more than a dozen hospitals, I have never seen any attempt to clean the internal airflow path or been informed of any such procedure.

3. Violation of EU Medical Devices Directive (MDD")

Medical devices in the UK and throughout the EU are governed by the MDD. Annex 1 of the MDD sets forth the Essential Requirements that each device must meet before achieving *Conformité Européenne* ("CE") and receiving the CE Mark. Essential Requirements include:

- The devices must be designed and manufactured in such a way that, when used under the conditions and purposes intended, they will not compromise the health or safety of patients, users or other personnel.
- Safety principles must be utilized for the design and construction, and they should include state-of-the-art technologies.
- The devices must meet all claimed performance criteria.
- The devices must continue to function as intended, without compromising safety or health, when subjected to normal conditions of use.

The Bair Hugger system fails to meet each of these Essential Requirements. When used as intended—in the operating theatre—the system compromises the safety

of patients by spewing bacteria into the patients' open surgical wounds. By failing to include a hose-end filter to capture aerosolized bacteria, as researchers have demanded since 1997, Arizant has ignored safety principles and avoided even basic technological protections. Under normal conditions of use, the blowers incubate pathogenic bacteria and blow the bacteria into the sterile field, clearly compromising the safety of patients.

Clause 13.6(h) of Annex I addresses issues identical to those addressed by the FDA in 21 CFR 801:

> If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses.

As noted above, instructions to wipe the outside of the blower with a damp cloth does not even purport to address the issue of internal contamination.

Section 8.1 of the MDD also addresses the issue:

> **8.1 Infection and Microbial Contamination**
>
> The devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties, the design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.

A system that incubates pathogens, blows those pathogens into the surgical site, and is impossible to clean is hardly "designed in such a way as to eliminate or reduce…the risk of infection…."

D. Culpability of Arizant

While Arizant may have been aware of the contamination risk created by Bair Hugger blowers even prior to October 2007, the facts were explicitly laid before Arizant executives at the annual meeting of the American Society of Anesthesiologists in San Francisco October 13-17, 2007. In a brochure and video presentation entitled "Blowing Air Is Risky," (Annex E) Arizant competitor Hot Dog International LLC publicly presented the following facts:

- A department of public health in the U.S. called Bair Hugger blowers "reservoirs of infection."
- Particle counters measured more than 50 million bacteria-sized particles per hours spewing from Bair Hugger blowers.
- An outbreak of multi-drug resistant *Acinetobacter* had been traced to the inside of Bair Hugger blowers, as reported in *Infection Control and Hospital Epidemiology*.
- Germ colonies could be cultured by swabbing inside Bair Hugger units and by impacting the air blown from the hose on a culture plate.

Copies of the brochure were provided to employees of Arizant during the meeting. (Affidavit of Dr. Scott Augustine, Annex F.)

In response to the Blowing Air Is Risky brochure, Arizant filed suit against Hot Dog International in Germany. In papers filed with the German court, Arizant repeatedly attacked the validity of the peer-reviewed, published research and asserted that any problem with contamination could be traced to the failure of Arizant's customers to change filters as required. (German documents are available upon request.) For example, Arizant alleged:

- Bair Hugger blowers were only a "possible" source of the *Acinetobacter* outbreak at Leiden University Medical Centre. (In fact, the authors stated that the data suggested that Bair Hugger blowers were "indeed the source of the outbreak.")
- The *Acinetobacter* outbreak could not be blamed on Bair Hugger because the filters were not changed on schedule. (In fact, dirty filters should further restrict airflow, reducing—rather than increasing—airborne contamination.)
- The study conducted by microbiologists at Stanford University was not scientifically valid. (The study selected for publication by the American Society of Anesthesiologists.)
- Arizant inexplicably defended itself against Dr. Beavers' "reservoirs of infection" statements by explaining that the article and speeches identified Bair Hugger blowers as only one of several "reservoirs of infection," not the only one.

After Hot Dog International provided proof to the German court regarding the accuracy of each statement, Arizant recast its claim as an objection to the manner in which Hot Dog International made its statements, not the underlying accuracy of the statements themselves.

More recently, a law firm representing Arizant threatened a British medical devices distributor with litigation if the distributor did not stop informing customers of the research relating to FAW. (Dechert letter at Annex G)

Rather than encourage scientific research concerning contaminated Bair Hugger blowers, Arizant seems to be attempting to thwart such research. Recently an employee of Arizant threatened Prof. Leaper with "repercussions" if revelations of the risks of FAW did not cease. (Statement of Steve Hammant-Stacy, Annex H) In May, Arizant's vice-president of sales, Robert Buehler, contacted Prof. Leaper in England, offering financial assistance if Leaper would conduct research on behalf of Arizant. (Statement of Robin Humble, Annex I.) Shortly thereafter, Prof. Leaper notified his research team that he would not do any more research on FAW contamination or laminar flow disruption. (Affidavit of Dr. Scott Augustine, Annex F)

In 2009, on the eve of research to be conducted by doctors that would have tested the Bair Hugger blowers located at University Hospital in Caen, France for contamination, Arizant quickly removed every Bair Hugger blower in the facility and replaced them with 80 new blowers. At an approximate retail price of $1,400, this cover-up cost Arizant more than $112,000. (Id.) Similarly, just before UK orthopedic surgeon Dr. Mike Reed was to begin testing the contamination levels of Bair Hugger blowers at a National Health Service Hospital in Northumbria, Arizant replaced all the hospital's blowers with new (and, obviously, uncontaminated) units. Id.

E. Recommendations

Although MedWatch does not specifically provide for Reporters to make recommendations concerning safety improvements, I will nevertheless make suggestions throughout this report. As regards the bacterial contamination, I recommend:

1. As demanded by several clinical researchers, Arizant and other manufacturers should be required to place a HEPA filter on the hose-ends of FAW blowers. As described below, this action would also bring FAW blowers into conformity with operating room ventilation standards promulgated by the Hospital Infection Control Practices Advisory Committee of the National Center for Infectious Diseases ("HICPA").

In its 1999 "Guideline for Prevention of Surgical Site Infections," HICPA urged that inside operating theatres, hospitals should "filter all air, re-circulated and fresh, through the appropriate filters per the American Institute of Architects' recommendations."[xliii] That 1996 guideline was updated by the 2005 Standard 170, *Ventilation of Healthcare Facilities* produced by the American Society of Heating, Refrigerating and Air-Conditioning Engineers ("ASHRAE").

Standard 170 covers all equipment used for heating air in healthcare facilities. For inpatient surgery facilities, double filtration is required, as has been recommended by several Bair Hugger researchers. Filter bank No. 1 (inlet filtration) must achieve MERV

8 (40-50% efficiency) and filter bank No. 2 (outlet filtration) must achieve MERV 14 (90% efficiency). Moreover, at Sec. 5.7.2, the ASHRAE standard states:

> All air distribution devices shall meet the following requirements:
>
> a) Surfaces of air distribution devices shall be suitable for cleaning.
>
> b) The supply diffusers in Class B & C surgeries shall be designed and installed to allow for internal cleaning.

2. FAW air-circulation systems should be required to meet all aspects of ASHRAE Standard 170, including those listed above. Since "internal cleaning" is impossible, however, both inlet and outlet filters should be HEPA. Otherwise, pathogens will continue to breed inside the blowers and be blown into the sterile field.

3. Contaminated blowers should be recalled from the field and decontaminated before being put back into service.

4. Warning labels should be required, identifying the risk of internal contamination.

II. Degradation of filtration

Two models of Bair Hugger blowers can be found in the field. In the United States and around the world, tens of thousands of the Model 505, introduced in the early 2000s, remain in use. The Model 750 blower became available a few years ago, and all new Bair Hugger blowers sold since by Arizant have been Model 750s.

A. Misrepresentations to the FDA

In an effort to obtain 510(k) clearance for its Model 750 blower, Arizant successfully established substantial equivalence between the Model 750 and its predecessor, the Model 505. In a communication received by the FDA on September 6, 2000 identified as K001149, Arizant represented to the FDA that the filtration of the Model 750 was "HEPA," an improvement over the " .2 micron filter" of the Model 505. (Annex J) The US Centers for Disease Control defines a HEPA (High Efficiency Particulate Air) filter as an air filter that removes more than 99.97% of particles 0.3 microns or larger.[xiv]

Until recently, the filtration efficiency of the Model 505 was 93.8%. As certified by an independent laboratory, however, replacement filters for the Model 505 have recently been reduced to 63.8 % efficiency. Similar testing revealed that the filter in the Model 750 blower achieves only 61.3% efficiency. (Annex K) The previously mentioned two studies conducted by Prof. Leaper's group (one of which has been

accepted for publication by the *American Journal of Infection Control*) revealed average filtration efficiencies to be 61.3% and 63.8% respectively.

This degradation of filtration efficiency by Arizant apparently occurred after Arizant's executives were informed of the contamination of their blowers at the October 2007 annual meeting of the American Society of Anesthesiologists. Arizant, however, had long known that inadequate filtration can lead to contamination of the surgical field. In a letter to the FDA regarding its cardiac FAW blanket received on June 26, 1997 identified as K964673, Arizant admitted that "air blown intraoperatively across the surgical wound may result in airborne contamination." (Annex L) Arizant successfully argued, however, that wound infections would be avoided because "[all] Bair Hugger Blankets designed for use in the operating room feature a tape barrier which prevent (sic) air from migrating toward the surgical site." Id.

While the statement regarding the universality of a tape barrier may have been true when made, it is true no longer. At least seven models of Bair Hugger blanket (generally called the "Underbody Series") do not even attempt to contain contaminated air within the taped edge of the blanket. Instead, they blow contaminated air directly toward the surgical field.[xv] Also, my personal experience shows that the tape barrier frequently becomes dislodged during preparation for surgery.

Even Arizant's 1997 representation that the tape barrier could contain the contaminated air was erroneous. In fact, the hot air escapes near the floor, mixes with dirty air and rises (even against laminar flow) into the sterile field. (See video attached as Annex M and Section III, below.)

B. Other misrepresentations by Arizant

According to the Inadvertent Perioperative Hypothermia Costing Report prepared by the NHS's Purchasing and Supply Agency ("PASA") in the UK, a distinguishing feature among FAW devices is the "…presence of an air filter capable of removing very small (0.2-0.3 micron) airborn particles from the air drawn into the device, as an infection control measure."[xvi]

Based on this false belief, both NICE and MHRA have concluded that Bair Hugger blowers do not present a risk of infection. The false belief arises from representations by Arizant in its published Product Specifications that Bair Hugger filtration is "high efficiency" (HEPA) (Annex N) as well as direct representations to MHRA and PASA. As explained above, these representations are false. Moreover, former engineering and product development employees of Arizant have stated in an affidavit filed with the German court as follows:

- The inlet filtration of Bair Hugger blowers does not prevent contamination. The majority of blowers cultured were contaminated with bacteria.
- Some forced air blowers emit large numbers of 0.3-0.5 micron particles. Up to 50 million particles per hour blowing from the hoses have been measured.
- The warm, dry interior of forced air blowers does not kill all pathogens. (Annex O)

In 2008, after clinicians throughout the UK were informed by Dr. Augustine, the inventor of Bair Hugger therapy, of the risk of contamination created by FAW, Arizant's CEO, Gary Maharaj, wrote a widely disseminated letter, quoting a finding by NICE that "FAW systems are naturally built to eliminate bacteria." (Annex P). One can only assume that Maharaj knew the statement was inaccurate; he had been informed of the contamination problem in 2007. Moreover, a device with a filtration efficiency of 61.3% is barely built to reduce bacteria, much less "to eliminate bacteria."

In March 2010, Dr. Scott Augustine wrote Maharaj and Arizant's Chief Regulatory Officer, David Westlin, urging them to inform the FDA and European regulators of the contamination risk created by Bair Hugger blowers and to cease the fraudulent claims of HEPA filtration. (Annex Q). Arizant did not respond.

Arizant continues to make the same misrepresentations via the Internet. In a document on its website entitled, "Facts About Forced-Air Warming." Arizant purports to "address some inaccuracies about forced-air warming that makers of competing technologies are promoting." Once again, Arizant claims that Bair Hugger filtration is "high efficiency" (HEPA). (Annex R)

C. <u>Regulatory consequences</u>

As described in 21 CFR 807.81(a)(3), a new 510(k) application is required for changes to an existing device where the change could significantly affect the safety or effectiveness of the device. Arizant's failure to file a new 510(k) after downgrading its filter to 61.3% efficiency violates this standard.

The FDA requires that every modification to a device be reviewed by appropriate personnel in accordance with the 21 CFR 820 Quality System regulations. If the modification is determined to be insignificant, the decision must be documented with supporting data in the master file. If it is significant, a new 510(k) must be filed. Given the consequences of the degradation of the Bair Hugger filter, the change certainly required filing a new 510(k).

A proper analysis would have followed the protocols set forth in ISO Standard 14971, entitled "Medical devices — Application of risk management to medical devices." Sec. D.2.2.3 cites a situation exactly like that presented by Bair Hugger as

an example of systemic fault:

> inadequate environmental control, or a breakdown in environmental control systems, leads to contamination with a toxic substance or an infectious agent.

Sec. D.3 describes how to evaluate the level of risk. Given the often-catastrophic consequences of surgical infections, the following standard seems to apply:

> [F]or significant hazards, that is, hazards which could inflict harm of high severity…no level of exposure can be identified that corresponds to a risk so low that there is no need to bother about it. In such cases, the risk estimate should be made on the basis of a reasonable worst-case estimate of probability.

Since it did not file a new 510(k), Arizant either failed to perform a risk analysis at all or it performed the analysis inadequately. A calculation of Arizant's culpability should be influenced by Arizant's 1997 admission that "air blown intraoperatively across the surgical wound may result in airborne contamination" as well as by any financial gain that Arizant enjoyed as a result of the safety degradation.

Such culpability, in fact, could extend to illegal adulteration. Medical devices are subject to the adulteration provisions of Sec. 501 of the Food, Drug and Cosmetics Act. Specifically, Sec. 501(c) states that a device is adulterated if its quality falls below that which it purports or is represented to possess. Arizant represented to the FDA and to the public that the Model 750 Bair Hugger blower protected surgical patients from bacterial contamination with HEPA filtration. It then knowingly failed to meet that standard. Despite the degradation of safety, Arizant continues to claim high efficiency filtration. The FDA may assess monetary penalties for violations of Sec. 301(a) of the Act (the introduction or delivery "into interstate commerce of any … device … that is adulterated or misbranded") of up to $15,000 for each violation up to a total of $1,000,000.

D. Recommendations

Arizant should be required to restore the inlet filtration in its Bair Hugger blowers to HEPA standards. As noted above, an additional filter that conforms to ASHRAE Standard 170 should be installed distally at the hose end. Neither action, however, deals with the immediate issue: tens of thousands of Bair Hugger blowers that have become internally contaminated with pathogens because of the inadequate inlet filtration. All such blowers should be recalled from the field and be internally decontaminated before being put back into service.

III. Destruction of Laminar Flow protection

A. Importance of Laminar Flow

According to a study cited by the Centers for Disease Control, laminar flow ventilation reduces SSIs by more than 50%--from 3.4% to 1.6%. [xvii] In a study of 435 patients undergoing Austin Moore hemiarthroplasty, the rate of re-operation for all indications in the non-laminar airflow theater group was four times greater than in the laminar airflow group. Similarly, the use of laminar flow reduced infection rates after posterior spinal fusion.[xviii]

Laminar flow is especially important in orthopedic surgery—where a single airborne bacterium has been shown to be able to infect implanted foreign material such as a prosthetic knee or hip.[xix] For that reason, current CDC recommendations include performing orthopedic implant operations under laminar flow.[xx]

Similarly, a 2003 article by Farhad Memarzadeh, PhD, PE, chief of technical resources in the Division of Engineering Services at the National Institutes of Health, concluded:

> Systems that provide laminar flow regimes represent the best option for an operating room in terms of contamination control, as they result in the smallest percentage of particles impacting the surgical site.[xxi]

B. Impact of FAW on Laminar Flow

Observations during the above-cited research lead to concern about the impact of the "waste" hot air emitted from FAW blowers—particularly on laminar flow ventilation during ultra-clean surgery. In general, a FAW blower produces 1,000 watts of heat energy per hour. Only about 50 watts are transferred to the patient; the rest escapes from under the surgical drape near the floor, then rises through the dirty air located near the floor and into the laminar flow. The air then cools and dumps the contaminated air into the sterile field. (A visualization of this appears in the video attached as Annex M)

Similarly, this phenomenon can be observed in the blog[xxii] and YouTube videos[xxiii] posted by Drs. Reed and McGovern – orthopedic surgeons and researchers in Northumbria, UK. In these experiments, they used "neutral buoyancy" bubbles (small soap bubbles filled with a mixture of air and helium which is adjusted to produce neutral buoyancy), to show the air currents created by rising waste heat from FAW.

Additional research regarding the destruction of laminar flow protection by waste heat from FAW blowers includes the following:

1.) "Forced Air Warming versus Conductive Fabric Warming – An Evaluation of Conventional (non-laminar, positive pressure) Operating Room Ventilation Disruption," a recent study in submission for publication in the *Annals of Surgery*, was authored by a team including myself and Drs. M. Reed and P McGovern. The effect of waste heat was studied in a conventional (non-laminar, positive pressure) operating room ventilation environment. FAW was compared with conductive fabric warming (CFW), with and without a surgeon by the table. Tracer smoke was introduced near the floor under the operating table. The degree of ventilation penetration and disruption was determined by the percentage of smoke detected in the air directly above the surgical site. The results:

* With a surgeon present, forced air warming (FAW) on "high" heat resulted in a large increase in the percentage of tracer-laden air from under the operating table detected at the surgical site versus FAW ambient control (63.0% v 6.9%).
* With a surgeon present, conductive fabric warming (CFW) on "high heat" resulted in no increase in the percentage of tracer-laden air detected at the surgical site versus CFW ambient control (4.9% v 6.1%).
* The use of forced air warming was found to generate sufficient waste heat to disrupt conventional OR ventilation and mobilize tracer contaminated air from under the table upwards and into the surgical site. Detected particle counts showed that in the presence of a single surgeon, the waste heat from FAW on "high" could mobilize sufficient quantities of tracer-laden floor air, so that more than half of the air directly above the surgical site consisted of potentially pathogenic floor air. (Annex S)

2.) "Forced Air Warming versus Conductive Fabric Warming – An Evaluation of Laminar Operating Room Ventilation Disruption" a recent study in submission for publication in the *British Journal of Orthopedics*, was authored by a team including myself and Drs. M. Reed and P McGovern. We compared the effects of two patient warming modalities classified as having "low waste heat load" (conductive fabric warming - "CFW") and "high waste heat load" (forced air warming – "FAW") on laminar ventilation performance. Neutral buoyancy soap bubbles ("bubbles") were used to visualize airflows and particle counts of tracer smoke were performed 15 cm above the surgical site to quantitatively assess tracer mobilization into the surgical site. The results:

* Vented waste heat from FAW use at 43°C created warm-air convection currents that mobilized tracer particulate upwards against the downward laminar flow and into the surgical site, as indicated by bubbles.

* With no surgical staff, the use of FAW at 43°C resulted in a ≈30-fold increase in particle counts at the surgical site versus controls.

* With a surgical staff present, the use of FAW at 43°C resulted in a ≈90-fold increase versus controls.

* CFW use at 43°C produced minimal waste heat and had no effect on airflow currents or particle counts at the surgical site versus controls.

* Conclusion: The use of FAW generated sufficient waste heat to form convection currents that disrupted laminar ventilation performance and mobilized tracer contaminated air into the surgical site from high pathogenic-risk locations near the floor and under the drape. Bubbles showed the sheltered space between the surgeon's body and operating table as the primary area these convection currents form. (Annex T)

3.) In a abstract submitted to the American Academy of Orthopedic Surgeons 2011 annual meeting by Drs. M Reed and P McGovern, FAW was compared with conductive fabric blankets (CFB) in its effect on laminar flow ventilation. Airflow was visualized with neutral buoyancy bubbles introduced under a torso warming blanket at the head end of the table. The findings:

* There was no contamination of the surgical site when using CFB.

* A significant increase in laminar ventilation disruption was detected using Poisson regression for FAW v CFB with no ether screen (6 v 0 bubbles over the surgical site; $p<0.01$).

* A very significant increase in laminar ventilation disruption was detected using Poisson regression for FAW v CFB with a half height ether screen (146 v 0 bubbles over the surgical site; $p<0.01$).

* FAW disrupts laminar ventilation performance and mobilized potentially contaminated under-drape air against the downward laminar flow and into the surgical site.

C. Arizant's knowledge of the risk

In October 2009, at the annual meeting of the American Society of Anesthesiologists held in New Orleans, Arizant was informed of the disruption of laminar flow protection caused by the waste hot air exhausted by Bair Hugger blowers. The video (Annex M) was watched several times by Arizant Chief Scientist Al Vanduren, whose comments included, " I didn't know that," and "I didn't think the air would do that." Other Arizant executives watched the video as well. (Affidavit of Scott Augustine, Annex F)

D. Arizant's response

Ignoring its own observations and scientific evidence to the contrary, Arizant's webite assures clinicians that the contaminated air cannot reach the surgical site because,

"Air velocity within the operating theatre is many times stronger than that of the forced-air warming blanket." (Annex R)

Arizant has even begun running advertisements in UK medical publications, further attempting to obfuscate the issue. (Annex U). In response to concerns that waste hot air from Bair hugger blowers disrupts the protection of laminar flow, Arizant's advertisement states:

> While simple logic makes it clear that forced air warming has no impact on laminar conditions, science also supports this. A forced air warming blanket delivers less than one percent of the airflow of a laminar flow system and therefore is unable to affect laminar flow ventilation systems." (Emphasis added) (Id.)

If disruption of laminar flow were a mere marketing issue, Arizant's misdirection might be acceptable, perhaps even clever. The issue, however, is patient safety, and Arizant has an obligation to be honest rather than clever. A comparison of airflow is irrelevant. The fundamental issue is waste heat, not waste air. The physics are simple: heat rises. Almost all of the 1000+ watts of heat/energy generated by the Bair Hugger blower escapes near the floor, mixes with dirty air, rises into the laminar flow and falls into the sterile field. (Annexes M and T).

E. Additional evidence

Other recent evidence adds to the concerns about airborne contamination during surgery. For example, in one of a series of articles published in *Interface*, the Journal of the UK's Royal Society, researchers wrote:

"In hospital operating theatres, the convective flows could spread infection and pose a real threat to the outcome of surgery." [xxiv]

Finally, a Ph.D. dissertation published by University Of Leeds engineering student Katherine A. Roberts under the supervision of surgical air-quality expert Prof Clive Beggs investigated the likelihood of airborne dissemination of *Clostridium difficile*. She stated that " the aerial dissemination of *C. difficile* in hospitals contributes to the spread of disease, accompanied by the contact route." [xxv]

Her conclusion:

> The evidence for the aerial dissemination of *C. difficile* discussed in this thesis suggests that the high rates of CDI

> experienced in UK hospitals and around the globe may be due to the aerial dissemination route increasing environmental contamination. Id.

Although the evidence that FAW spreads *C. difficile* is far less developed than evidence regarding other pathogens, Roberts's conclusion underlines the importance of protecting surgical patients from aerosolized bacteria.

E. Recommendations

Unlike the previous issues raised in this Report, the destruction of the protection of laminar flow ventilation by waste heat has no easy solution. Waste heat is an inescapable by-product of FAW. At a minimum, therefore, the FDA should require that the labels and instructions for FAW blowers contraindicate their use in orthopedic implant and other ultra-clean surgeries employing laminar flow protection.

IV. Violation of reprocessing standards

A. Contaminated blowers placed in hospitals

Of the tens of thousands of Bair Hugger blowers loaned (or leased without charge) to US hospitals, many thousands have been refurbished or remanufactured by Arizant. That is, after several years of use, the units were returned to Arizant for repair, were refurbished, then returned to the field for use in other hospitals with their serial numbers prefaced with an "R." (Affidavit of Dr. Scott Augustine, Annex F)

Remanufacturing and refurbishment at Arizant includes replacing filters and hoses, checking electronics and cleaning the exterior of the blower as needed. The interior air-flow path of the blower, however, is not cleaned. In fact, without complete disassembly of the device, it cannot be cleaned. Id. The obligation of a re-manufacturer, however, is to return the medical device to its original specifications. 21 CFR 820 In this case, it certainly requires that Arizant clean the contaminated interior of the devices.

Upon original placement in the field, the air-flow path of a Bair Hugger blower is clean and uncontaminated. As studies funded by Arizant have shown, such pristine blowers do not add to the bacterial load in operating theatres. However, the research cited herein establishes that after significant use, the airflow paths of the blowers become heavily contaminated with pathogens.

Arizant places refurbished, but contaminated, FAW blowers in operating theatres as if they were new. The hospitals' biomedical engineers, having no way to check the cleanliness of the sealed interior of the blowers, certify them for use. In this manner, pathogenic contamination from one hospital can spread to others.

B. Recommendation

All refurbished "R" Bair Hugger blowers should be recalled from the field and be internally decontaminated. If internal decontamination is not possible, use of refurbished blowers should be prohibited.

V. Failure to Meet FDA Reporting Obligations

A. Arizant's failure to file an MDR

The FDA requires that a manufacturer report via the Medical Device Reporting (MDR) system when the manufacturer becomes aware of information reasonably suggesting that one of its marketed devices has malfunctioned and that such malfunction has or would be likely to contribute to a serious injury. 21 CFR Sec. 803.3(q) A malfunction is a failure of the device to meet its performance specifications or to otherwise perform as intended. 21 CFR Sec. 803.3(m) A malfunction is reportable if it compromises the device's therapeutic effectiveness or if it could contribute to a serious injury or a significant adverse device experience. Id. A device may have contributed to such an event, among other reasons, because of improper or inadequate device design. 21 CFR Sec. 803.3(d) A manufacturer has become aware of a reportable event when a person with management or supervisory responsibilities becomes aware of the event from any source. 21 CFR Sec. 803.3(c)

Even if unaware previously, Arizant learned that its blowers spread pathogenic contamination no later that October 2007, at the annual meeting of the American Society of Anesthesiologists. Arizant learned that waste heat from its blowers destroys the protection of laminar flow and dumps dirty air into the surgical field no later than October 2009, again at the same annual meeting. All of these facts, as well as published peer-reviewed evidence, were reiterated in Dr. Augustine's letter to Arizant CEO Gary Majaraj dated April 2, 2010.

Despite this information, Arizant has not filed an MDR or provided any other information to the FDA. Presumably, Arizant will defend its inaction by noting that no hospital has reported a surgical infection traced specifically to a contaminated Bair Hugger blower.

Such, however, is not the standard. As noted above, a malfunction is reportable if it could contribute to a significant adverse experience. Destroying the

protection of a surgical laminar flow system is a significant adverse device experience even if no infection occurs. In orthopedic implant surgery contamination by a single bacterium can lead to infection.[xxvi] With such a risk, Arizant's awareness that Bair Hugger systems do not meet their own filtration specifications and blow millions of particles into the surgical field certainly created a reporting obligation. The failure to report is a prohibited act, and renders the device misbranded. FDCA §§ 301(q)(1), 502(t), 21 U.S.C. §§ 331(q)(1), 352(t)

Given that the FDA cited Arizant with Form FDA 483 in January 2010 for failing to properly report injuries, the company should be acutely aware of its responsibilities under the MDR system. (Annex V)

B. Recommendation

Arizant should incur the full penalties that can be levied by the FDA for its repeated failure to report risks to patient safety.

Conclusion:

I request that the FDA carefully review the evidence attached and fully investigate the issues raised. If the FDA confirms the accuracy of the facts and analysis I have provided, I ask that the FDA act quickly to protect vulnerable surgical patients, particularly those undergoing orthopedic or other ultra-clean surgery.

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